OCT 2 1 2004

K033523

510(K) SUMMARY

Collagen-ORC Antimicrobial Matrix

Submitter's Name and Address:	Johnson & Johnson Medical Ltd. Gargrave Skipton North Yorkshire BD23 3RX United Kingdom
Contact Person	John D. Paulson, Ph.D. Vice-President, Regulatory Affairs and Quality Assurance Johnson & Johnson Wound Management A division of Ethicon, Inc. Telephone: (908) 218-2887 Fax: (908) 218-2734 e-mail: jpaulson@ethus.jnj.com
Name of Medical Device	Classification Name: Dressing, Wound Common/Usual Name: Dressing Proprietary Name: Collagen-ORC Antimicrobial Matrix
Substantial Equivalence	Collagen-ORC Antimicrobial Matrix is substantially equivalent to: PROMOGRAN Matrix Wound Dressing (K014129) Manufactured by Johnson & Johnson Medical, Ltd., Gargrave, SKIPTON, BD23 3RX, United Kingdom AQUACEL-Ag with Hydrofiber (K013814) Manufactured by ConvaTec, A Division of E.R. Squibb and Sons, LLC
Device Classification	Currently wound dressings containing animal derived materials are unclassified by U.S. Food and Drug Administration's Center for Devices and Radiological Health

Device Description

Collagen-ORC Antimicrobial Matrix is a sterile primary dressing comprised of freeze-dried composite of 55 % collagen, 44 % ORC, 1 % silver-ORC. Silver-ORC contains 25 % w/w ionically bound silver.

Indications for Use

The Collagen-ORC Antimicrobial Matrix is intended for the management of exuding wounds.

Under the supervision of a health care professional, Collagen-ORC Antimicrobial Matrix may be used for the management of:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full-thickness & partial thickness wounds
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds

Collagen-ORC Antimicrobial Matrix may be used under compression therapy with healthcare professional supervision.

Safety

Biocompatibility studies have demonstrated the Collagen-ORC Antimicrobial Matrix to be non-toxic, non-irritating, non-sensitizing, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2004

John D. Paulson, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
Johnson & Johnson Wound Management
Route 22 West
P.O. Box 151
Somerville, New Jersey 08876

Re: K033523
Trade/Device Name: Collagen – ORC Antimicrobial Matrix
Product Code: FRO
Dated: July 22, 2004
Received: July 23, 2004

Dear Dr. Paulson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033523

Indications for Use

510(k) Number (if known): k033523

Device Name: Collagen-ORC Antimicrobial Matrix

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K033523